

PART 1 – Administrative Information

JUL 21 2006

II. 510(k) SUMMARY

A. Product Information

Rapid Diagnostics, a division of MP Biomedicals, LLC, has developed two additional drug-of-abuse tests kits for the detection of oxycodone and buprenorphine in human urine samples. These two test strips complement the current panel for DOA analysis, the **MICROMEDIC® Drugs of Abuse Panel Test** (K033566). The **MICROMEDIC® Drugs of Abuse Panel Test** is an immunochromatographic one-step in vitro diagnostic test designed for the qualitative determination of up to nine (9) drug substances in human urine specimens to include amphetamines, barbiturates, benzodiazepine, cocaine, methadone, methamphetamine, opiates, phencyclidine (PCP) and cannabinoid (THC).

As will be demonstrated in the following three sections (Parts I, II, and III), both the **MP RapidOXY Test Strip** and the **MP RapidBUP Test Strip** are similar in format and intended use as the parent **MICROMEDIC® DOA Panel Test**. There are to be added to the existing test panel once cleared.

Both the **MP RapidOXY Test Strip** and the **MP RapidBUP Test Strip** are based on the principle of specific immunochemical reaction between antibodies and antigens to analyze particular compounds in human urine specimen. The tests rely on the competition for antibody binding between drug conjugate and free drug which may be present in the urine specimen being tested.

MP RapidOXY Test Strip and MP RapidBUP Test Strip
Premarket Notification

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B. Intended Use:

1. Oxycodone

The ***MP RapidOXY Test Strip*** is an immunochromatography based one step in vitro test. It is designed for qualitative determination of oxycodone in human urine specimens above a cut-off level of 100 ng/ml. Each oxycodone test kit is used to obtain a visual, qualitative result and is submitted for point-of-care (POC) use. It is not intended for over the counter sale to lay persons.

The assay will provide a preliminary analytical test result, with recommended follow-up using gas chromatography/mass spectrometry (GC/MS) for a confirmatory result.

2. Buprenorphine

The ***MP RapidBUP Test Strip*** is also an immunochromatographic, one-step in vitro test. It is designed for qualitative determination of buprenorphine's metabolite, buprenorphine-3-beta-d-glucuronide, in human urine specimens above a cut-off level of 10 ng/ml.

As with the oxycodone test kit, the buprenorphine kit is used to obtain a visual, qualitative result and is submitted for point-of-care (POC) use. It is not intended for over the counter sale to lay persons. In addition, the assay will provide only a preliminary analytical test result, with recommended follow-up using GC/MS.

MP RapidOXY Test Strip and MP RapidBUP Test Strip
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C. **Name of Manufacturer:** Rapid Diagnostics, Inc. 1429 Rollins Road, Burlingame, California, USA, a division of MP Biomedicals, LLC, hereafter RAPID DIAGNOSTICS.

D. **Principle**

The ***MP RapidOXY Test Strip*** and the ***MP RapidBUP Test Strip*** are based on the principle of specific immunochemical reaction between antibody and antigen to analyze particular compounds in human urine specimens. The assays rely on the competition for binding antibody between drug conjugate and free drug which may be present in urine. When drug is present in the urine specimen, it competes with drug conjugate for the limited amount of antibody-dye conjugate.

When the amount of drug is equal or more than the cut-off (i.e., 100 ng/ml oxycodone or 10 ng/ml buprenorphine-3- β -d-glucuronide, or B-3- β -d-G), it will prevent the binding of drug conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result.

A control line is present in the test window to work as procedural control in both assays. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

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E. Submission Summary

In this Premarket Notification [510(k)], RAPID DIAGNOSTICS, Inc. will present information for clearance of the following two devices, the MICROMEDIC® ***MP RapidOXY Test Strip*** and the ***RapidBUP Test Strip***, for use in a POC setting. The submission will consist of three parts, Part I, II and III, to include Administrative Information, the Performance Data and the Accuracy Data, respectively.

The submission consists of the required administrative and technical information, along with a detailed presentation of the clinical and laboratory data used to substantiate the POC claim.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MP Biomedicals, LLC.
c/o Ms. Robin J. Hellen
Hellen Professional Services
9418 Lasaine Avenue
Northridge, CA 91325

JUL 21 2006

Re: k051958

Trade/Device Name: RapidBUP Test Strip
RapidOXY Test Strip

Regulation Number: 21 CFR§ 862.3650

Regulation Name: Opiate test system

Regulatory Class: Class II

Product Code: DJG

Dated: June 15, 2006

Received: June 26, 2006

Dear Ms. Hellen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

MP RapidOXY Test Strip and MP RapidBUP Test Strip
Premarket Notification

STATEMENT FOR INDICATIONS FOR USE (BUPRENORPHINE)

510(k) Number (if known): K051958

Device Name: RapidBUP Test Strip

Indications for Use:

The *MP RapidBUP Test Strip* is an immunochromatography based one step in vitro test. It is designed for qualitative determination of the major metabolite of buprenorphine, buprenorphine-3-β-d-glucuronide, in human urine specimens at cut-off level of 10 ng/ml.

The *MP RapidBUP Test Strip* may be used in a point-of-care (POC) setting and will provide preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Concurrence of the CDRH, Office of In-Vitro Diagnostic Device (OIVD)

Prescription Use: X

OR

Over the Counter Use: _____

A. L. S. (Signature)
Division Sign-Off

Diagnostic
Safety

K051958

MP RapidOXY Test Strip and MP RapidBUP Test Strip
Premarket Notification

STATEMENT FOR INDICATIONS FOR USE (OXYCODONE)

510(k) Number (if known): K051958

Device Name: RapidOXY Test Strip

Indications for Use:

The *MP RapidOXY Test Strip* is an immunochromatographic one-step *in-vitro* test designed for qualitative determination of oxycodone in human urine specimens above a cut-off level of 100 ng/ml.

The *MP RapidOXY Test Strip* may be used in a point-of-care (POC) setting and will provide preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Concurrence of the CDRH, Office of In-Vitro Device (OIVD)

Prescription Use: X

OR

Over the Counter Use: _____

Albert Gault
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

OK: K051958